GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:747
ANSWERED ON:07.02.2017
Land of Sick Pharma Companies
Kothapalli Smt. Geetha

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Drug Controller General of India (DCGI) has recently issued warning regarding the use of antibiotic medicines amid the news of death of one person because of its use and has asked the drug manufacturers to issue warning related to its use;

(b) whether the chemists have also been asked not to supply these medicines without doctor"s prescription and if so, the details thereof; and

(c) the details of the steps taken by the Government to do away with discrepancies prevailing in drug industry and medicine shops?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) & (b): Drug Controller General of India (DCGI) has informed that they have recently issued a Notice dated 16.01.2017 to all State/ UT Drugs Controller, Zonal/Sub-Zonal Offices of CDSCO and Pharma/ Consumer Associations advising them to follow strict requirements of Schedule H and H1 for sale of drugs including antibiotics, which are as follows:
1. Schedule H: if it contains a substance specified in Schedule H it is to be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and also be labelled with the following words-
Schedule H drug − warning: To be sold by retail on the prescription of a Registered Medical Practitioner only;
..2/-

2. Schedule H1: if it contains a drug substance specified in Schedule H1, the drug formulation shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and also be labelled with the following words in a box with a red border-
"SCHEDULE H1 DRUG − WARNING;
- It is dangerous to take the preparation except in accordance with the medical advice.

- Not to be sold by retail without the prescription of a Registered Medical Practitioner."

(c): Under Drugs and Cosmetics Act & Rules, 1945, manufacture for sale, and sale for distribution of drugs are regulated by the State Licensing Authority and appointed by the State Government. State Licensing Authority is empowered to take actions in case of non-compliance with any provisions of the said Act and Rules.

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